

# Design and execution of a Verification, Validation, and Uncertainty Quantification plan for a numerical model of left ventricular flow after LVAD implantation

## Supporting Material 1

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### S1 Ranking for risk informed credibility assessment

This section provides the gradation for each credibility factor and actions required on each item in the standard ASME V&V40 [1].

1. **VERIFICATION:** Activities related to the correctness of the implementation of the numerical model.

1.1. **Code verification:** Activities to ensure the correct implementation of the code.

1.1.1. **Software quality assurance (SQA):** Activities to ensure repeatability and traceability of the code modifications. Ranked in three:

- A. Very little or no software quality assurance (SQA) are followed.
- B. SQA procedures are specified and documented.
- C. SQA procedures are specified and documented. Quality metrics are tracked. Code anomalies are systematically registered and tracked.

1.1.2. **Numerical code verification (NCV):** Activities related to demonstrate the correct implementation and functioning of the numerical algorithms. Ranked in four:

- A. No NCV was performed.
- B. The numerical solution is compared to a benchmark solution from another code.
- C. The numerical solution is compared to an exact analytical or manufactured solution, demonstrating an asymptotical approach with mesh size.
- D. The order of accuracy is compared to the theoretical order of accuracy in an exact solution.

1.2. **Calculation verification:** Estimate the numerical error in the quantity of interests (QoIs) due to spatial and temporal discretisation.

1.2.1. **Discretisation error:** Estimation of error due to the finite points in time/space in which the problem is solved. Ranked in three:

- A. No space/time convergence analysis is performed.
- B. Space and time convergence analysis are performed obtaining stable behaviours.
- C. Grid and space convergence analysis is performed, estimating the discretisation error.

1.2.2. **Numerical solver error:** Errors originated from the numerical solution based on the solver parameters.

- A. No solver parameter sensitivity was performed.
- B. Solver parameters are based on values from a previously verified model.

- C. A solver parameter sensitivity study is performed ensuring that the chosen values does have a negligible impact in the final model accuracy.

1.2.3. **User error:** refers to errors accrued by the practitioner (unchecked inputs).

- A. Inputs and outputs were not verified.
- B. Key inputs and outputs were verified by the practitioner.
- C. Key inputs and outputs were verified by an internal peer review.
- D. Key inputs and outputs were verified by reproducing simulations by an external reviewer.

2. **VALIDATION:** Process of assessing the degree to which the computational model is an appropriate representation of the reality for the context of use.

2.1. **Computational model:** Refers to the input of the numerical model.

2.1.1. **Model form:** Refers to the correctness of the conceptual and mathematical formulation of the computational model. Ranked on three:

- A. Influence of the model assumptions are not explored.
- B. Influence of some assumptions is explored.
- C. Influence of every assumption is explored.

2.1.2. **Model inputs:** Refer to the values of parameters used.

2.1.2.1. **Quantification of sensitivities:** examines the degree to which the model's output is sensitive to the model inputs. Ranked on three:

- A. A sensitivity analysis is not performed.
- B. A sensitivity analysis of the expected key parameters is performed.
- C. Comprehensive sensitivity analysis is performed.

2.1.2.2. **Quantification of uncertainties:** the degree to which known or assumed uncertainties in the model inputs are propagated to uncertainties in the simulation. Ranked in four:

- A. Uncertainties are not quantified.
- B. Uncertainties on expected key inputs are identified and quantified but not propagated to assess the effect in the QoIs.
- C. Uncertainties on expected key inputs are identified, quantified and propagated to assess the effect in the QoIs.
- D. Uncertainties on all inputs are identified and quantified and propagated to assess the effect of the simulation results.

2.2. **Comparator:** Is the data against which the simulation results are evaluated.

2.2.1. **Test samples:** Refers to the population and characteristics of the experimental subjects.

2.2.1.1. **Quantity of test samples:** examines the number of samples used. Ranked in three:

- A. A single sample is used.
- B. Multiple samples are used, but not being statistically relevant.
- C. A statistically relevant number of samples are used.

2.2.1.2. **Range of characteristics of test samples:** This item examines the number of test conditions used. Ranked in four:

- A. A single test condition is examined.
- B. Test conditions in a nominal range are examined.
- C. Extreme test conditions are examined.
- D. The entire range of test conditions is examined.

2.2.1.3. **Measurements of test samples:** Evaluate the rigor with which the measurement data characterize each test sample. Ranked in three:

- A. The test sample is not characterized (measured).
- B. One or more key characteristic are measured.
- C. All key characteristics are measured.

2.2.1.4. **Uncertainty of test samples measurements:** This factor examines the analysis of the uncertainty associated with the tools and methods used. Ranked in four:

- A. Characteristics uncertainty not addressed.
- B. Uncertainty analysis incorporates instrument accuracy only.
- C. Uncertainty analysis incorporates instrument accuracy and statistics (repeated measurements).

2.2.2. **Test conditions:** evaluate the rigorousness in which the tests were executed.

2.2.2.1. **Quantity of test conditions:** Number of test conditions imposed and characterized. Ranked in two:

- A. Single test condition.
- B. Multiple test conditions.

2.2.2.2. **Range of test conditions:** evaluates the range of test conditions included in the comparator study. Ranked in four:

- A. A single test condition is examined.
- B. Test conditions representing a range of conditions near nominal range are examined.
- C. Test conditions representing the expected extreme conditions are examined.
- D. Test conditions representing the entire range of conditions is examined.

2.2.2.3. **Measurements of test conditions:** Examines the rigor with the measurement data that characterize the test conditions. Ranked in three:

- A. The test conditions are not measured.
- B. One or more key test conditions are measured.
- C. All key test conditions are measured.

2.2.2.4. **Uncertainty of test conditions:** This component analyses the uncertainty associated with the tools and methods to characterize the test conditions. Ranked in four:

- A. Test conditions were not characterized or their uncertainty analysis is not executed.
- B. Uncertainty analysis of the test conditions characteristics incorporated instrument accuracy only.
- C. Uncertainty analysis of the test conditions characteristics incorporate instrument accuracy and statistics (repeated measurements).

2.3. **Assessment:** of the accuracy of the simulation output.

2.3.1. **Equivalence of input parameters:** between the type and range of input parameters. Ranked in three:

- A. The types of some inputs are dissimilar.
- B. The types of all inputs are similar, but ranges were not equivalent.
- C. The types and ranges of all inputs are similar.

2.3.2. **Output comparison:** Equivalency between the types of output from the computational model and those from the comparator leads to increased credibility.

2.3.2.1. **Quantity:** Quantity of Qols to compare. Ranked in two:

- A. A single output is compared.
- B. Multiple outputs are compared.

2.3.2.2. **Equivalence of output parameters:** Referring to the types of outputs to be compared. Ranked in three:

- A. Most types of outputs are dissimilar.
- B. Most types of outputs are similar.
- C. Most types of outputs are equivalent.

2.3.2.3. **Rigor of output comparison:** This refers to the method used to compare the Qols from the computational model:

- A. Visual comparison is performed.
- B. Comparison is performed by arithmetic difference.
- C. Uncertainty in the output of the computational model or the comparator was used.

2.3.2.4. **Agreement of output comparison:** qualitative or quantitative agreement between the Qols in the computational model and the comparator:

- A. The level of agreement is not satisfactory for key comparison.
- B. The level of agreement is satisfactory for some key comparisons.
- C. The level of agreement is satisfactory for all comparisons.

3. **APPLICABILITY:** Attains the relevance of the validation to support the use of the model for a determined Context of Use.

3.1. **Relevance of the Quantities of Interest for the Question of Interest:** this compares the Qols from the validation activities to the Qols for the context of use (CoU). Ranked in three:

- A. The Qols from validation are related but not identical to those for the CoU.
- B. A subset of the Qols from the validation are identical to those for the CoU.

- C. The Qols from the validation are identical to those for the CoU.
- 3.2. **Relevance of the validation activities to the CoU:** This factor summarizes the relative proximity of the CoU to the validation points. Ranked in four:
  - A. There was no overlap between the ranges of the validation points and the CoU.
  - B. There was partial overlap between the ranges of the validation points and the CoU.
  - C. The CoU encompassed some validation points.
  - D. The CoU encompassed all validation points.

## References

- [1] American Society of Mechanical Engineers. Assessing Credibility of Computational Modeling through Verification and Validation: Application to Medical Devices - V V 40 - 2018. Asme V&V 40-2018. 2018; p. 60.